REMARKS

The present response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Status of Claims

Claims 1-45 are pending in the application. Claims 1-20 have been rejected. Claims 21-45 were withdrawn. No claim is canceled herein. Claim 16 is amended herein. Support for this amendment can be found, at least, in the claims as filed.

CLAIM REJECTIONS

Rejections Under 35 U.S.C. § 112, Second Paragraph

In the Office Action, the Examiner rejected claim 16 as being indefinite. Specifically, the Examiner notes that independent claim 1 recites risperidone, but its dependent claim 16 recites other compounds, and thus it is unclear with respect to the components of drug in claim 16. In response, Applicants have amended claim 16 and the amended claim recites "said drug further comprises." As a result, claim 16 fully clarifies the components of drug. Accordingly, Applicants believe that this rejection is moot, and thus Applicants respectfully request withdrawal of the rejection.

Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-13 and 15-20, under 35 U.S.C. § 103, as allegedly being obvious over Siegel (U.S. Patent Application Publication No. 2002/0179096; "Siegel") in view of Kino *et al* (U.S. Patent No. 5,871,778; "Kino"). Specifically, the Examiner asserts that Siegel teaches a surgically implantable drug delivery device for long-term delivery of the antipsychotic drug – haloperidol. The Examiner acknowledges that Siegel does not teach risperidone, but relies on Kino for this feature. Accordingly, the Examiner finds that it would have been obvious to combine the references to arrive at the invention. Applicants respectfully disagree for the reasons set forth below.

Applicants submit herewith a Declaration ("Declaration"), under 37 CFR § 1.132, from Dr. Steven Siegel. Dr. Siegel is the first-named inventor in the Siegel reference, which is relied upon by Examiner for the rejections discussed herein.

Applicants note that independent claim 1 recites "biodegradable polymer comprises a poly(lactide/glycolide) (PLGA) copolymer at a concentration of about 40-90% (w/w)" and "drug comprises risperidone, 9-OH-risperidone, or an active metabolite thereof at a concentration of about 10-60% (w/w)." As discussed in the Declaration, nowhere does Siegel teach or suggest this combination of claimed features. Rather, Siegel relates to haloperidol loaded implant, not risperidone loaded implant as claimed.

As discussed in the Declaration, Kino does not cure the defect in Siegel. Specifically, Kino relates only to bromperidol or haloperidol loaded into dl-Polylactic acid or Poly(lactic-co-glycolic) acid (50:50) for making a microcapsule, which is not an implant as claimed. Although Kino describes a laundry list of active materials including risperidone, it provides no data or support for how much of each active ingredient that can be loaded in to each biodegradable polymer. Therefore, as discussed in the Declaration, at the maximum, Kino provides a general guidance for producing only a microcapsule with no expectation of success with respect to specific amount of drug for each combination of the drug and the polymer for an implant.

Applicants note that, as discussed in the Declaration, it is well known in the art that concentrations are, in fact, critical for making a polymer-based drug implant because of possible saturation and subsequent crystallization of the drug. Therefore, it would be unreasonable to expect initial theoretical drug concentrations of 10% or more, without any data.

In addition, as discussed in the Declaration, a combination of a drug and a polymer may exhibit differing physio-chemical properties at various concentrations, and thus one could not expect or predict whether the arrangement and/or conformation of molecules in the crystal lattice would change while combining the drug and the polymer during solvent casting or other approaches to form an implant. Therefore, an attempt to incorporate as much as 10-60% risperidone into the PLA:PGA copolymer, as claimed in the subject Application cannot be expected in view of the Kino reference or any other reference in the art. Accordingly, it

would not have been obvious to modify Siegel's implant based on the Kino's laundry list of active materials.

Furthermore, as discussed in the Declaration, surprisingly and unexpectedly, the release of risperidone was achieved at the loading concentrations of 10%-60%. *See* Example 7 of the Specification.

Since Kino does not teach or suggest how to arrive at the claimed 10%-60% risperidone and 40%-90% of the biodegradable polymer, Kino does not render the claimed invention obvious.

Accordingly, neither Siegel nor Kino, either alone or in combination, teach or suggest all the features of the claimed invention. Therefore, Applicants respectfully request withdrawal of the rejection.

In the Office Action, the Examiner rejected claims 13 and 14, under 35 U.S.C. § 103(a), as allegedly being obvious over Siegel in view of Kino and further in view of Sidman (U.S. Patent 4,352,337) ("Sidman"). In response, Applicants note that claims 13 and 14 are dependent claims that ultimately depend from and add additional features to independent claim 1. Since independent claim 1 is patentable for the reasons discussed above, dependent claims 13 and 14 are also patentable by virtue of there dependency. Accordingly, Applicants respectfully request removal of this rejection.

CONCLUSION

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

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